

WHAT IS CLAIMED IS:

- 1 1. A method of treating a relapsed cancer in a mammal, said method
2 comprising administering to said mammal a pharmaceutical composition comprising a
3 liposome-encapsulated vinca alkaloid.
- 1 2. The method of claim 1, wherein said relapsed cancer is a
2 lymphoma or leukemia.
- 1 3. The method of claim 1, wherein said relapsed cancer is a non-
2 Hodgkin's Lymphoma.
- 1 4. The method of claim 1, wherein said non-Hodgkin's Lymphoma is
2 a member selected from the group consisting of low grade non-Hodgkin's Lymphoma,
3 intermediate grade non-Hodgkin's Lymphoma, follicular lymphoma, large cell
4 lymphoma, B-cell lymphoma, T-cell lymphoma, Mantle cell lymphoma, Burkitt's
5 lymphoma, NK cell lymphoma, and acute lymphoblastic lymphoma.
- 1 5. The method of claim 1, wherein said vinca alkaloid is vincristine.
- 1 6. The method of claim 1, wherein said vinca alkaloid is selected
2 from the group consisting of vinblastine, vindesine, and vinorelbine.
- 1 7. The method of claim 1, wherein said liposome comprises
2 distearoylphosphatidylcholine.
- 1 8. The method of claim 7, wherein said liposome further comprises
2 cholesterol.
- 1 9. The method of claim 1, wherein said liposome comprises
2 sphingomyelin.
- 1 10. The method of claim 9, wherein said liposome further comprises
2 cholesterol.
- 1 11. The method of claim 1, wherein said liposome comprises a pH
2 gradient.

- 1 12. The method of claim 11, wherein the pH gradient is such that the
2 pH is lower at the interior of said liposome than at the exterior of said liposome.
- 1 13. The method of claim 1, wherein said mammal is a human.
- 1 14. The method of claim 1, wherein said mammal has previously
2 undergone at least one chemotherapy treatment.
- 1 15. The method of claim 14, wherein said at least one chemotherapy
2 treatment comprised administration of a free-form vinca alkaloid.
- 1 16. The method of claim 15, wherein said free-form vinca alkaloid is a
2 member selected from the group consisting of vincristine, vinblastine, vindesine, and
3 vinorelbine.
- 1 17. The method of claim 14, wherein said at least one chemotherapy
2 treatment comprised administration of an anthracycline-containing combination regimen.
- 1 18. The method of claim 17, wherein said anthracycline is doxorubicin.
- 1 19. The method of claim 14, wherein said mammal has exhibited a
2 partial response or a complete response to said chemotherapy prior to the relapse of said
3 cancer.
- 1 20. The method of claim 19, wherein said relapse is a second relapse.
- 1 21. The method of claim 1, wherein said liposome-encapsulated vinca
2 alkaloid is administered systemically by intravenous delivery.
- 1 22. The method of claim 1, wherein said liposome-encapsulated vinca
2 alkaloid is co-administered with at least one additional chemotherapeutic agent.
- 1 23. The method of claim 22, wherein said at least one additional
2 chemotherapeutic agent is a member selected from the group consisting of
3 cyclophosphamide, doxorubicin, prednisone, and combinations thereof.
- 1 24. The method of claim 1, wherein said liposome-encapsulated vinca
2 alkaloid is co-administered with at least one additional anti-tumor agent.

- 1 25. The method of claim 24, wherein said additional anti-tumor agent
2 is a monoclonal antibody.
- 1 26. The method of claim 25, wherein said monoclonal antibody is a
2 member selected from the group consisting of Rituxan™, Oncolym™, and Bexxar™.
- 1 27. The method of claim 24, wherein said additional anti-tumor agent
2 is an antisense drug or an anti-tumor vaccine.
- 1 28. The method of claim 5, wherein said vincristine is administered at
2 a dosage of between about 1.4 to about 2.4 mg/m² to said patient.
- 1 29. The method of claim 5, wherein said vincristine is administered to
2 said patient once every 7-21 days.
- 1 30. The method of claim 29, wherein said vincristine is administered to
2 said patient once every 14 days.
- 1 31. A method of treating a non-Hodgkin's Lymphoma in a patient, said
2 method comprising administering to the patient a pharmaceutical composition comprising
3 a liposome-encapsulated vinca alkaloid, wherein said composition is free of cardiolipin.
- 1 32. The method of claim 31, wherein said vinca alkaloid is vincristine.
- 1 33. The method of claim 31, wherein the dosage of said vinca alkaloid
2 is greater than about 1.4 mg/m².
- 1 34. The method of claim 33, wherein said dosage is between about 1.4
2 to about 2.4 mg/m².
- 1 35. The method of claim 33, wherein said composition is administered
2 to said patient once every 7-21 days.
- 1 36. The method of claim 35, wherein said composition is administered
2 to said patient once every 14 days.
- 1 37. The method of claim 31, wherein said vinca alkaloid is a member
2 selected from the group consisting of vinblastine, vindesine, and vinorelbine.

- 1 38. The method of claim 31, wherein said liposome comprises a
2 neutral lipid.
- 1 39. The method of claim 31, wherein said liposome comprises
2 distearoylphosphatidylcholine.
- 1 40. The method of claim 39, wherein said liposome further comprises
2 cholesterol.
- 1 41. The method of claim 31, wherein said liposome comprises
2 sphingomyelin.
- 1 42. The method of claim 41, wherein said liposome further comprises
2 cholesterol.
- 1 43. The method of claim 31, wherein said liposome comprises a pH
2 gradient.
- 1 44. The method of claim 43, wherein the pH gradient is such that the
2 pH is lower at the interior of said liposome than at the exterior of said liposome.
- 1 45. The method of claim 31, wherein said non-Hodgkin's Lymphoma
2 is a relapsed non-Hodgkin's Lymphoma.
- 1 46. The method of claim 31, wherein said patient has previously
2 undergone at least one chemotherapy treatment.
- 1 47. The method of claim 46, wherein said at least one chemotherapy
2 treatment comprised administration of a free-form vinca alkaloid.
- 1 48. The method of claim 47, wherein said free-form vinca alkaloid is a
2 member selected from the group consisting of vincristine, vinblastine, vindesine, and
3 vinorelbine.
- 1 49. The method of claim 46, wherein said at least one chemotherapy
2 treatment comprised administration of an anthracycline-containing combination regimen.
- 1 50. The method of claim 49, wherein said anthracycline is doxorubicin.

- 1 51. The method of claim 46, wherein said patient has exhibited a
2 partial response or a complete response to said chemotherapy treatment prior to the
3 relapse of said non-Hodgkin's Lymphoma.
- 1 52. The method of claim 31, wherein said liposome-encapsulated vinca
2 alkaloid is administered by systemic delivery.
- 1 53. The method of claim 52, wherein said systemic delivery comprises
2 intravenous delivery.
- 1 54. The method of claim 31, wherein said liposome-encapsulated vinca
2 alkaloid is co-administered with at least one additional chemotherapeutic agent.
- 1 55. The method of claim 54, wherein said at least one additional
2 chemotherapeutic agent is a member selected from the group consisting of
3 cyclophosphamide, doxorubicin, prednisone, and combinations thereof.
- 1 56. The method of claim 31, wherein said liposome-encapsulated vinca
2 alkaloid is co-administered with at least one additional anti-tumor agent.
- 1 57. The method of claim 56, wherein said additional anti-tumor agent
2 is a monoclonal antibody.
- 1 58. The method of claim 57, wherein said monoclonal antibody is a
2 member selected from the group consisting of Rituxan™, Oncolym™, and Bexxar™.
- 1 59. The method of claim 56, wherein said additional anti-tumor agent
2 is an antisense drug or anti-tumor vaccine.
- 1 60. A method of treating a transformed cancer in a mammal, said
2 method comprising administering to said mammal a pharmaceutical composition
3 comprising a liposome-encapsulated vinca alkaloid.
- 1 61. The method of claim 60, wherein said transformed cancer is a non-
2 Hodgkin's Lymphoma.
- 1 62. The method of claim 60, wherein said vinca alkaloid is vincristine.

1 63. The method of claim 60, wherein said liposome comprises
2 sphingomyelin and cholesterol.

1 64. A method to treat a neoplasia in a mammal, said method
2 comprising administering to said mammal a liposome-encapsulated vinca alkaloid in a
3 dosage of from about 1.4 to about 2.4 mg/m².

1 65. The method of claim 64, wherein said vinca alkaloid is
2 administered to said mammal once every 7-21 days.

1 66. The method of claim 65, wherein said vinca alkaloid is
2 administered to said mammal once every 14 days.

1 67. The method of claim 64, wherein said vinca alkaloid is co-
2 administered to said mammal with a prophylactic or therapeutic treatment for
3 neurotoxicity.

1 68. A kit for use in the treatment of a neoplasia in a mammal, said kit
2 comprising components useful in the preparation of a liposome-encapsulated vinca
3 alkaloid, instructions for preparing the liposome-encapsulated vinca alkaloids, and
4 instructions for the use of the liposome-encapsulated vinca alkaloids in the treatment of
5 said neoplasia.

1 69. The kit of claim 68, wherein said kit comprises at least three vials,
2 wherein one of the vials contains vincristine sulfate, a mannitol buffer, and sodium
3 acetate, wherein one of the vials contains liposomes comprising sphingomyelin and
4 cholesterol suspended in a citrate buffer, and wherein one of the vials contains an alkaline
5 phosphate buffer.

1 70. A kit for use in the treatment of a neoplasia in a mammal, said kit
2 comprising a stable formulation of liposome-encapsulated vinca alkaloids and
3 instructions for the use of the liposome-encapsulated vinca alkaloids in the treatment of
4 said neoplasia.